REMARKS

The above-captioned patent application has been carefully reviewed in light of the Official Action to which this Amendment is responsive. Claims 1, 3 and 6 have been amended in an effort to further clarify and distinctly point out that which is regarded as the present invention. To that end, it is believed no new matter has been added.

Claims 1-6 and 10 are pending, Claims 7, 8 and 11-25 have been subjected to a Restriction Requirement. Each of the pending claims have been rejected based on certain prior art. In addition, Claims 1-6, 9 and 10 have been rejected under 35 USC §112, 2nd paragraph, for formal issues. The disclosure has also been objected to, based on formal matters. Applicant respectfully requests reconsideration based on the amended claims and specification, as well as the following discussion.

Turning to the prior art rejections, Claims 1-5 and 9, 10 have been rejected under 35 USC §102(b) as being either anticipated or in the alternative rendered obvious under 35 USC §103(a) based upon Kang et al. (U.S. Patent No. 5,728,587). Applicant respectfully traverses the above rejection.

In order to anticipate under the Statute, each and every claimed limitation must be found or its structural equivalent in the cited art. Those limitations or features that are claimed and not found in the cited art must be notoriously well known to one of sufficient (i.e., ordinary) skill in the field of the invention.

To maintain a "prima facie" obviousness rejection under the Statute, each and every essentially claimed limitation must be found in or suggested by the prior art that is cited, either singly or in combination. Those features that are not found must be notoriously well known in the field of the invention to one of sufficient (i.e., ordinary) skill. In interpreting the claims and unless Applicant intends a different meaning, the ordinary or "plain" meaning of the term is used for purposes of understanding the meaning or definition of the term. Extrinsic references, such as dictionaries, can be used in order to determine the ordinary meaning of the term unless the patentee intended a specific or different definition for that term(s).

The present invention defines a biosensor that can qualitatively or quantitatively analyze components in which the components can be measured more accurately and in a simpler and more expedient manner. These objects can be achieved according to the present invention: i) without previous separation of the components, such as blood cells, being required; ii) without employment of a particular apparatus; and iii) without being affected by colored components, such as blood pigments, in analyzing an analysis target in an inspection target solution that contains colored components, such as red blood cells.

To that end, the present invention provides a biosensor comprising a development layer that is provided with a bleaching agent area where a reagent having bleaching action is carried in a dry state that is dissolvable. According to the present invention, when an inspection target solution having colored components reaches the bleaching reagent area, colored components of the solution are faded by the bleaching agent reacting with the colored components, and consequently the shade of area on the reactive layer, except the detecting area, is suppressed. That is, in the present biosensor, a bleaching reagent area carrying a bleaching reagent in the dry state is provided at a chromatographically upstream location, and colored components in the inspection target solution are faded due to the action of the bleaching reagent with the now-faded inspection target solution being developed in the chromatographically downstream direction, with the color of the reactive layer of the biosensor being suppressed. By use of the present biosensor, which qualitatively or quantitatively measures color reactions on the reactive layer, it is therefore possible to minimize the influences by the background that are caused by the presence of color components in the inspection target solution, these influences being capable of inhibiting the readings of the coloring reactions. Therefore and for visual judgments or measurements using a measuring device, it is now possible to realize a simple, quick and more accurate measurement that neither requires the work of previously removing colored components nor employment of a particular structure.

With this background of the present invention, Applicant would like to now elaborate upon essential differences that exist between the primary cited reference of Kang et al. '587 (Kang) and the present invention. An object of Kang is to provide a device that detects the presence of analyte in a sample of biological fluid, the device employing an immunochemical receptor assembly and a filter medium that is specifically selected, treated and disposed. An exemplary immunochemical assay device, as taught by Kang, includes a reservoir pad, a first and second filter element and a wicking membrane containing an immobilized substance, each of which are disposed on a substrate. With regard to the first and second filter elements, it is disclosed that the first filter element produces specific ligand receptor complexes therein, while the second filter element is operable to permit the specific ligand receptor complexes pass therethrough, but hindering the passage of larger components contained in the original sample, or produced in the first filter element (see col. 3, lines 42-50 of Kang).

It is further disclosed in Kang that auxiliary reagents can be provided that are useful to enhance the specificity of the ligand receptor complexes that are generated and bound or increase the number of the complexes and thereby increase the sensitivity of the assay device. It is further disclosed that these auxiliary reagents can be included in either the first or the second filter element, and as these reagents can include but are not limited to buffers, detergents, and anticoagulants (see Kang, col. 6, line 61 through col. 7, line 3).

Though the buffers and detergents listed in Kang are useful to enhance the specificity or increase the number of ligand receptor complexes and hence increase the sensitivity of the assay device, these reagents do not operate in the same way as the bleaching reagent as required according to the present invention. The Examiner has indicated that because the present claims lack a specific definition for bleaching reagents and only discuss a bleaching action, the buffer and detergent taught by Kang are an equivalent to the bleaching reagent that is disclosed in the present invention. However, as is apparent from the above content taught by Kang, reading the reference in its entirety for the stated purpose of these auxiliary reagents, it is

clear that the buffers and detergents taught by Kang as useful only to enhance the specificity of the ligand receptor complexes and increase the number of the ligand receptors and hence increase the sensitivity of the assay device, but that these materials do not perform a bleaching function. Referring to Fig. 6 of Kang, an embodiment is depicted and described in which the development solution containing the buffer solution is applied to a storage pad to be developed, in order that the separation of the blood corpuscle components in the whole blood that is added onto the filter element and development thereof should be performed. However, it is not at all disclosed in Kang that the buffers and detergents operate to perform as a bleaching reagent having a bleaching function to fade out the blood cell components-derived pigments. In fact, it is understood in this embodiment that a change of color in the indicia zone can be prevented in that the blood corpuscle components are separated by the second filter element. Summarily, then Kang is advantageous in that, while analyzing the whole blood sample, filtering of large substances from the whole blood is performed in a state where the whole blood is held in its whole integrally, and a membrane that permits only the liquid components to pass therethrough is selected as a second filter element, thereby enabling the indicia zone, and causing no change in color. While advantageous, the above functionality is quite different from that of the present invention in which blood cell components in the inspection target solution may not be filtered, but the blood pigments are faded out to be developed on the reaction layer, without being influenced by the derived pigments of the blood cell components.

The Examiner has further argued that the present disclosure lacks a specific definition for the bleaching reagents. However, as described above, bleaching reagents in accordance with the invention have a bleaching function for fading the colored components in the inspection target solution. Applicant herein believes the plain and ordinary meaning of the term "bleach" should be regarded, wherein the function to bleach the blood pigments is a bleaching function, and the bleaching reagents are reagents which function to bleach the blood pigments, such as in the case of blood.

In support of same and with reference to the Oxford Dictionary of English, the meaning of the term "Bleach" is to "clean or sterilize (a drain, sink, etc.) with bleach. The above term is used both as a noun and as a verb in this context. As a noun, the term "bleach" refers to "a chemical (typically a solution of sodium hypochlorite or hydrogen peroxide) use to make materials whiter or for sterilizing drains, sinks, etc". As such, the term in its accepted and customary meaning is used in the present context for the bleaching reagents and for the bleaching functionality of the reagents – that is, to fade out colors. It is respectfully noted herein that the above term is widely and generally known throughout the world.

Applicant therefore believes that the Examiner's arguments concerning the equivalence of the buffer and detergent of Kang with the bleaching reagent according to Claim 1 of the present invention to be improper given that the auxiliary reagents of the Kang device clearly do not perform a bleaching function. The auxiliary reagents are used for entirely different purposes, as noted above, and in addition, the Kang device has no apparent need for such functionality. Hence, no such functionality would be apparent to one of ordinary skill reviewing Kang in its entirety. In order to define the invention more clearly, however, Applicant has herein amended Claim 1 to more clearly specify the bleaching function in light of the common definition noted above. That is, the bleaching action/function of the bleaching reagent is now clarified to state that this action is for fading colored components in a liquid sample. Support for the foregoing amendments is provided, as discussed above, and in the present application. Claims 3 and 6 have also been amended to now comport with the amended language of Claim 1. To that end, we believe no new matter has been added.

In summary and because Kang fails to describe or otherwise suggest a bleaching reagent having a bleaching function, this reference can neither anticipate or provide an obviousness rejection with regard to Claim 1. Claims 2-5 and 9, 10 are also believed to be allowable for the same reasons, since these claims depend therefrom. Reconsideration is respectfully requested.

Claim 6 has been rejected under 35 USC §103(a) as being obvious based on the combination of Kang and Kitajima (EP 0 785 430A1). Applicant respectfully traverses this rejection.

As noted above and in order to maintain a successful prima facie obviousness rejection, each and every claimed limitation must be found or its equivalent in the cited art, either singly or in combination. Those limitations that are not found must be notoriously well known in the prior art as a whole to one of ordinary skill in the field. In addition, there must be a motivation in the prior art as a whole to make the purported combination. This combination cannot be made through impermissible hindsight (i.e., advance knowledge) of the present invention through a piecemeal combination of features. To that end, the entirety of each reference should be considered to determine whether essential teachings of either reference would be seriously impaired or destroyed through the purported combination.

Kitajima discloses a method for separating plasma or serum sample from whole blood by adding an HL agent, including such as an inorganic salt, an amino acid and an amino acid salt. Kitajima (EP 0 785 430 A1) claims priority based upon a prior Japanese publication 9-196908. In the referenced Japanese application, it is clearly disclosed that the HL agent performs the function of accelerating separation between blood cells and blood plasmas to decrease the hematocrit value (Kitajima, page 3, lines 33-35). Examples described therein as having effects include NaCl, $CsCl_2$, Li_2SO_4, $CaCl_2$, Rb_2SO_4, and $CsSO_4$, but it is clear that none of these agents have a bleaching function for fading colored components in the inspection target solution, and thus they are not bleaching reagents according to the present invention. The other exemplary examples, i.e., such as Sly, Ala, Asp, and Glu as amino acids, which are also taught by Kitajima, similarly do not have a bleaching function for fading colored components in the inspection target solution, and thus these agents are also not bleaching reagents. Moreover, while Kitajima discloses a hydrogen salt such as $NaHCO_3$ (Kitajima, page 3, lines 36-43), it is clear that $NaHCO_3$ cannot provide the effects in the present invention, as described below.

In the present invention, sodium percarbonate is disclosed as an exemplary reagent that provides a bleaching function. Sodium percarbonate ($2Na_2CO_3\ 3H_2O_2$) is dissolved in water and is separated into sodium carbonate and hydrogen peroxide. Subsequently, hydrogen peroxide will be separated into active oxygen and water to present an oxidizing power, and resolves pigments into colorless components. This reaction in which the colored components are resolved into colorless components is one presenting a bleaching function, and sodium percarbonate is generally used as bleaching reagent in that reaction.

However, while $NaHCO_3$ (sodium bicarbonate) is a weak-alkaline reagent and is used as detergent, its resolution reaction is presented by a chemical reaction of $2Na_2CO_3 \rightarrow 2Na_2CO_3+H_2O+CO_2$, which would not generate a compound such as hydrogen peroxide that has a strong bleaching action. Therefore, it should be understood that though sodium bicarbonate might be useful as a detergent, this reagent is not at all effective as a bleaching reagent as intended by the present invention and more specifically according to Claim 1, as amended, for the bleaching function defined therein. Therefore, even if sodium bicarbonate in Kitajima were to be employed, the present invention cannot be obtained or cannot be easily conceived, even if Kang and Kitajima were to be combined. Applicant therefore believes that the Examiner's position as "one of ordinary skill in the art would have had a reasonable expectation of success in adding the HL agent of Kitajima to the device of Kang" cannot be accepted and a prima facie obviousness rejection cannot be maintained.

As described above, Kang and Kitajima, even if combined, do not suggest the construction of the present invention, i.e., a construction in which in a biosensor using chromatography, a bleaching reagent area where bleaching reagent is carried in its dry state is disposed at a chromatographically upstream position, colored components in the inspection target solution are faded by the bleaching function of the bleaching reagent, and the faded inspection target solution is developed toward the chromatographically downstream direction in a state of the color of the reaction layer being suppressed.

Therefore, it is clear that all of the essentially claimed features of Claim 1 are not found, even in the combination of Kang and Kitajima. Since Claim 6 is dependent upon Claim 1, it is believed this claim is also patentably distinct and reconsideration is therefore respectfully requested.

With regard to the Section 112 rejections, Applicant has now amended Claim 1 to clarify that the marker reagent part and the reagent immobilization part are each located on the development layer. Support is provided in the drawings, which indicates the development layer as a single layer or a multiple layer. The marker reagent part and the reagent immobilization part are separately disposed on the development layer.

It is believed the claims are now sufficiently clear and distinctly describe and particularly point out that which is regarded as the present invention. Reconsideration is respectfully requested.

Finally and regarding the formalities concerning the description, Applicant has amended the specification to remove all references therein to specific claims. Proper headings have also been added where appropriate to comport to proper US practice and the Abstract has also been amended to eliminate legal phraseology and provide a single paragraph format. To that end, it is believed no new matter has been added. Withdrawal of this objection is respectfully requested.

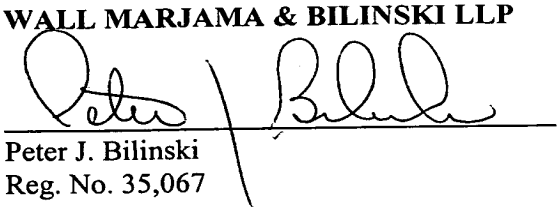
In summary, it is believed the above-captioned patent application is now in an allowable condition and such allowance is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicant's representative at the telephone number below.

The Director is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

WALL MARJAMA & BILINSKI LLP

By: 

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